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Proposed Re-evaluation Decision PRVD2010-15

Iodocarb

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the material preservative iodocarb, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing iodocarb in Canada.

An evaluation of available scientific information found that products containing iodocarb do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of iodocarb uses, new risk-reduction measures must be included on the labels of all products. Additional data are being requested at this time (Appendix I).

It should be noted that for end-use products containing more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

This proposal affects end-use products containing iodocarb registered in Canada for material preservative uses. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements. Note that wood uses of iodocarb are being reviewed together with all antisapstain active ingredients under a separate initiative within the PMRA and are not part of this re-evaluation decision.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for iodocarb and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of iodocarb.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health *and* the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Iodocarb, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the 1997 RED, the USEPA concluded that iodocarb was eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Is Iodocarb?

Iodocarb is an antimicrobial active ingredient that is used as a material preservative in textiles, adhesives, caulks, paints, latex paper coating, plastic, water-based inks, metal working fluids and a variety of consumer products (including household cleaning products). Iodocarb for use as a material preservative is applied by commercial workers during the manufacturing process. Commercial workers and homeowners can apply paint containing iodocarb using a brush, roller or an airless sprayer.

Iodocarb is also used for preservation of joinery wood products (e.g., window and door frames, decorative wood) and as a sapstain control chemical. Wood uses of iodocarb are not included in this re-evaluation.

Health Considerations

Can Approved Uses of Iodocarb Affect Human Health?

Iodocarb is unlikely to affect your health when used according to the revised label directions.

People could be exposed to iodocarb by working as a mixer/loader/applicator or by handling iodocarb-containing paint and while using iodocarb-treated products. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that iodocarb was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and similar risk-reduction measures are required.

Environmental Considerations

What Happens When Iodocarb Is Introduced Into the Environment?

Iodocarb is unlikely to affect non-target organisms when used according to the revised label directions.

The USEPA concluded that iodocarb use as a material preservative is unlikely to adversely affect the environment. These conclusions apply to the Canadian situation. Based on PMRA practices, general environmental hazard label statements are proposed by the PMRA.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of iodocarb, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Additional personal protective equipment (PPE) to further protect workers.
- Prohibit the use of iodocarb-treated materials for food packaging.
- Limit the use of iodocarb-treated textiles to non-apparel use only.
- Prohibit the use of iodocarb-treated textiles in residential settings,
- Prohibit the use of iodocarb-treated plastic for the production of children toys and other products which may come in contact with children (for example, plastic chair, plastic bottle).
- Additional good hygiene practices and proper cleaning/maintaining label statements.

Environment

- Advisory label statements

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix I lists all data requirements.

Next Steps

Before making a final re-evaluation decision on iodocarb, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, and a summary of comments received on the proposed decision and the PMRA's response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

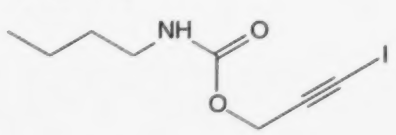
Iodocarb is an antimicrobial active ingredient registered for use as a material preservative (including textiles, adhesives, liquid detergents and metal working fluids), sapstain control and joinery wood preservative.

Following the re-evaluation announcement for iodocarb, the registrant(s) of the technical grade active ingredient in Canada indicated their intention to provide continued support for all material preservative uses included on the labels of commercial end-use products in Canada. Wood uses of iodocarb are not included in this re-evaluation because they are being reviewed with other antisapstain active ingredients under a separate initiative within the PMRA.

The Pest Management Regulatory Agency (PMRA) used the assessments of Iodocarb from the United States Environmental Protection Agency (USEPA) and data available to the PMRA. The USEPA Reregistration Eligibility Decision (RED) document for Iodocarb, dated 1997, as well as other information on the regulatory status of Iodocarb in the United States can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name		iodocarb (not approved by ISO)
Function		fungicide, material preservative, wood preservative
Chemical Family		carbamate
Chemical name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	3-iodoprop-2-yn-1-yl butylcarbamate
2	**Chemical Abstracts Service (CAS)**	carbamic acid, N-butyl, 3-iodo-2-propyn-1-yl ester
CAS Registry Number		55406-53-6
Molecular Formula		$C_8H_{12}INO_2$
Structural Formula		

Molecular Weight	281.09 amu
Purity of the Technical Grade Active Ingredient	97% minimum 97% nominal 99.5% nominal
Registration Number*	21750 28422 28583

* Reg. No. 24896 is not included in this review since it is a product registered under the Import for Manufacturing and Export Program (IMEP).

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 139, No. 24, SI/2005-114 (2005-11-30), including TSMP Track 1 substances, are not expected to be present in the product.

Impurities of human health or environmental concern as identified in Section 2.13.4 of Dir98-04 and Appendix II of Dir99-03 (excluding those identified in the Canada Gazette) are not expected to be present in the product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Table 1 Physical and Chemical Properties of the Technical Grade Iodocarb

Property	Result	Interpretation
Vapour pressure	0.1 – 3.8 x 10^{-3} Pa	Intermediate to low volatility
Ultraviolet (UV)/visible spectrum	Not expected to absorb at $\lambda > 300$ nm	
Solubility in water	146 – 174 mg/L	Very soluble in water. Concern for leaching.
n-Octanol/water partition coefficient	log K_{ow} = 2.3 – 2.88	Bioaccumulation is unlikely.
Dissociation constant	Does not dissociate in environmental pH range	

2.3 Comparison of Use Patterns in Canada and the United States

Iodocarb end-use products registered for use as a material preservative are applied during the manufacturing process to:

- paint at a maximum application rate of 0.16% a.i. in interior paint and 0.8% a.i. in exterior paint; end-use products formulated as a solution or powder;
- latex paper coating, adhesives and caulks at a maximum application rate of 0.8% a.i. in the final product; both liquid and powder formulations end-use products;
- plastic (including shower curtain, tarpaulins, umbrellas) at a maximum application rate of 1% a.i. in the final product; end-use products formulated as a solution only;
- metal working fluids at a maximum application rate of 0.25% a.i.; end-use products formulated as a solution only;
- textiles at a maximum application rate of 0.8% a.i. in canvases and cordage and 0.4% a.i. in other textiles (including carpets, drapes, shower curtains); both liquid and powder formulation end-use products;
- water-based inks at a maximum application rate of 1.2% a.i. in the final product; both liquid and powder formulation end-use products;
- consumer products (including household cleaning products) at a maximum application rate of approximately 0.05% a.i. in the final product; both liquid and powder formulation end-use products.

Based on the comparison of the Canadian use pattern with the uses registered in the US at the time of RED, it was determined that the USEPA RED encompasses all Canadian uses of iodocarb (except for the iodocarb use in consumer products). The Canadian formulation types, application methods and application rates are encompassed by those of the US.

On this basis, it was concluded that the USEPA RED for iodocarb is an adequate basis for the re-evaluation of uses of iodocarb in Canada.

All current material preservative uses of iodocarb are being supported by the registrant(s) and are considered in this re-evaluation. The antisapstain and joinery wood uses of iodocarb are being reviewed under a separate initiative within the PMRA with other antisapstain active ingredients; therefore, are not included in this document. Appendix II lists all iodocarb products that are registered for material preservation as of March 2, 2010, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 1997 RED, the USEPA concluded that the use of products containing iodocarb registered at the time of the RED publication would not pose unreasonable risks or adverse effects to humans or the environment and, therefore, are eligible for reregistration.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

3.1.1 Occupational Exposure and Risk Assessment

Based on available toxicity studies the USEPA determined that iodocarb can cause severe eye irritation but was of low toxicity via an oral, inhalation or dermal route. Iodocarb was not found to be a skin irritant.

Workers can be exposed to iodocarb when mixing, loading and/or applying the pesticide and when handling treated products.

The occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

For the short- /intermediate-term dermal exposure the toxicological endpoint was selected by the USEPA from a subchronic dermal study in the rat. For the long-term dermal and inhalation exposure the toxicological endpoint was selected from a chronic study in the rat (Appendix III).

A target MOE of 100 was considered to be protective for all exposure durations (taking into consideration an uncertainty factor of 10x for intraspecies variability and 10x for interspecies extrapolation).

3.1.1.1 Mixer/Loader/Applicator Exposure and Risk

Among the scenarios assessed in the USEPA RED, the following exposure scenarios were considered relevant to the Canadian situation:

- Mixing/loading of a liquid formulation in industrial settings
- Mixing/loading of a powder formulation in industrial settings
- Applying iodocarb-treated paints to surfaces using a paintbrush or an airless/compressed-air sprayer

The USEPA considered the duration of exposure to be short-/ intermediate-, and long-term for all material preservative uses except for the use in metal cutting fluids for which only short-intermediate-term exposure is expected.

Mixer/loader in industrial settings. The potential exposure of the mixer/loader in industrial settings was assessed by the USEPA using dermal unit exposure values from the Chemical Manufacturers Association (CMA) Antimicrobial Exposure Study. The study measured exposure of industrial workers wearing personal protective equipment (PPE) consisting of a long-sleeved shirt, long pants and chemical resistant gloves during mixing/transfer of antimicrobials to industrial systems. An additional assumption used in the risk assessment included a total amount of iodocarb used per day of 3.8 kg for an open pour scenario (for example, paint) and 12.7 kg for the liquid pump scenario (for example, metal working fluids).

The estimated combined (dermal plus inhalation) exposure doses for mixers/loaders of iodocarb (liquid and powder formulations) for application as a material preservative in industrial settings resulted in MOEs above the target MOE of 100, indicating no risk of concern. Based on the PPE used in the exposure study, similar PPE was required by the USEPA for workers handling iodocarb end-use products in industrial settings.

The RED adequately addressed exposure scenarios associated with the uses of Canadian products containing iodocarb in industrial settings. Therefore, based on the USEPA risk assessment and acute eye irritation properties of iodocarb, the PMRA proposes additional PPE consisting of a long-sleeved shirt, long pants and chemical-resistant gloves and eyewear for all workers handling iodocarb end-use products and for those involved in maintenance and repair activities. In addition, dust filtering respirator protection is required during handling if there is a potential for dust generation. The proposed label statements are listed in Appendix IV.

Commercial painter. The potential exposure of the applicator (painter) wearing single layer clothing and no gloves was assessed by the USEPA using dermal unit exposure values for the paintbrush and airless sprayer scenarios from the Pesticide Handlers Exposure Database (PHED). Additional assumptions used in this risk assessment included a maximum application rate of 1.2% a.i., a volume of paint applied of 19 L and 190 L for the paintbrush and airless sprayer scenario, respectively.

The estimated short-/intermediate- and long-term combined (dermal plus inhalation) exposure doses for the applicator using a paintbrush resulted in MOEs above the target MOE of 100, indicating no risk of concern. However, for the applicator using an airless sprayer, estimated combined (dermal plus inhalation) MOEs for all exposure durations were below the target MOE of 100, indicating a risk of concern. The USEPA believed that the calculated exposure dose was overestimated because workers were assumed to wear no gloves. Taking into consideration that commercial painters are likely to wear chemical-resistant gloves, the USEPA concluded that the painter exposure would not be of concern and no mitigation measures were required.

3.1.1.2 Post-application Exposure and Risk

The post-application occupational risk assessment considers exposures of workers handling materials/products to which iodocarb was added.

Workers handling textiles. Based on a qualitative risk assessment, the USEPA concluded that post-application exposure of workers handling textiles to which iodocarb was added during the manufacturing process should not be of concern. The USEPA conclusion is relevant to the Canadian situation. No further mitigation measures are being proposed.

Workers handling metal working fluids. Post-application occupational exposure of workers handling metal working fluids to which iodocarb was added and/or involved in maintenance/clean-up activities was not assessed by the USEPA due to the lack of exposure data. Therefore, in order to conduct a post-application risk assessment for workers handling metal working fluids the PMRA requires exposure data as a condition of continued registration. Data requirements are listed in Appendix I.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

Residential exposure is estimated using the MOE approach described in Section 3.1.1. The toxicological endpoints selected by the USEPA for assessment of risk from residential exposure are summarized in Appendix III.

Individuals in residential settings can be exposed to iodocarb when applying iodocarb-treated paint or while using iodocarb-treated products. In addition, toddlers can be exposed via incidental ingestion resulting from "object-to-mouth" activities (e.g., mouthing of a toy made with iodocarb-treated plastic).

Residential Painter. The USEPA estimated the potential exposure of homeowners applying iodocarb-treated paint by a paintbrush or an airless sprayer using unit exposure values from the PHED tables and assuming a maximum application rate of 1.2% a.i. The estimated exposure dose resulted in combined (dermal plus inhalation) MOEs above the target MOE of 100 for both application scenarios, indicating no risk of concern.

The USEPA determined also that exposure of individuals residing in an area recently painted with iodocarb-treated paint is expected to be negligible.

The USEPA conclusions regarding the use of iodocarb-treated paint by homeowners are considered relevant to the Canadian situation. No mitigation measures are proposed by the PMRA.

Individuals using consumer products. The PMRA concluded that post-application exposure of individuals to iodocarb in liquid detergents will be minimal based on low to intermediate iodocarb volatility. In addition, the PMRA believes that exposure of individuals to iodocarb used to preserve water-based inks, latex paper coatings, adhesives, and caulks will be negligible considering a low application rate of iodocarb in these products. No mitigation measures are proposed by the PMRA.

Individuals using treated textiles. The USEPA was unable to assess exposure of consumers to iodocarb in textiles (including carpets and drapes) due to the lack of adequate exposure data. Therefore, the PMRA proposes to limit the use of iodocarb-treated textiles to non-apparel use only and prohibit the use of iodocarb-treated textiles in residential settings. The proposed label statements are listed ion Appendix IV.

Incidental oral exposure of children. The potential incidental oral exposure of children to iodocarb resulting from "object-to-mouth" activity (e.g., mouthing a toy made with plastic to which iodocarb was applied) could not be fully assessed due to the lack of exposure data. Therefore, the PMRA proposes to prohibit the use of iodocarb-treated plastic for the production of children toys and other products which may come in contact with children (for example, plastic chair, plastic bottle). The proposed label statements are listed ion Appendix IV.

The USEPA also assessed post-application exposure of individuals in residential settings to treated wood. This assessment, however, is not considered relevant to the Canadian situation because the wood uses of iodocarb are being reviewed under a separate initiative within the PMRA together with other antisapstain active ingredients. These uses are not included in this document. Nonetheless, it should be noted that exposure of individuals in residential settings to iodocarb as a result of joinery wood treatment is expected to be negligible because the wood is treated during the manufacturing process and is used mainly for window and door components or exterior decorative wood joinery items.

3.1.2.2 Exposure from Food and Drinking Water

The USEPA concluded that exposure to iodocarb from food should not be of concern based on the fact that there are no food uses registered for iodocarb in the US. The USEPA believed that the potential exposure to iodocarb from drinking water is unlikely based on its rapid transformation in water.

The USEPA conclusions regarding dietary exposure are relevant to the Canadian situation. Based on the fact that none of the end-use product containing iodocarb was granted a "no objection status" by Health Canada, the PMRA recommends that the iodocarb product labels should include specific prohibition against the use of iodocarb treated products for food packaging. The proposed label amendments are listed in Appendix IV.

3.1.2.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to iodocarb, that is from food, water and residential exposures. Since Iodocarb is not registered for food uses and it is not expected to occur in drinking water, the USEPA concluded that residential uses are the only source of exposure which could be aggregated for this active ingredient.

The USEPA determined that there is a potential for aggregate exposure to iodocarb for individuals applying iodocarb-containing paint and using products to which iodocarb was added (for example, treated textiles). However it was determined that such exposure would be insignificant compared to that resulting from application of iodocarb-containing paint. On this basis, the USEPA concluded that aggregate risk would not be of concern based on acceptable risk for individuals applying iodocarb-containing paint.

The USEPA conclusions pertaining to aggregate exposure are relevant to the Canadian situation. While the assessed scenario did not account for exposure to consumer products, the PMRA concluded that the aggregate exposure from all Canadian uses of iodocarb is not expected to result in a risk of concern due to negligible exposure associated with the use of consumer products.

3.1.3 Cumulative Effects

The USEPA has not determined whether iodocarb has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Although, iodocarb is a carbamate, the USEPA did not determine if it should be considered with other carbamates in the assessment of cumulative effects. However, the USEPA believed that the contribution of iodocarb to the risks from other carbamate pesticides was likely to be minimal based on the registered use pattern.

3.2 Environment

3.2.1 Environmental Risk Assessment

Iodocarb is non-persistent in soil with a half-life of less than 3 hours in aerobic mineral soil. Nor is it persistent in the aquatic environment with half-life values of 139 days in pH 7 buffer solutions and less than 1 day in pH 9 buffer solutions. Iodocarb is expected to be mobile in mineral soils.

In water and soil, iodocarb transforms to propargyl butyl carbamate (PBC). An aerobic soil metabolism half-life of this transformation product is 4.31 days. Contamination of surface water and ground water is unlikely based on rapid transformation of iodocarb in water.
Iodocarb is not bioaccumulative based on log*Kow* values ranging from 2.3 to 2.88.

The USEPA determined that iodocarb is practically non-toxic to slightly toxic to birds, slightly toxic to small mammals, and highly to very highly toxic to both freshwater and estuarine/marine animals based on acute toxicity studies.

The USEPA conducted only a qualitative risk assessment for iodocarb and determined that environmental exposure associated with the use of iodocarb as a material preservative is expected to be minimal. No mitigation measures were required.

The USEPA's conclusions pertaining to the environmental exposure are relevant to the Canadian situation. In addition, the PMRA concluded that the use of iodocarb in consumer products is not expected to adversely affect the environment based on the low concentration of iodocarb in consumer products and the rapid transformation of this chemical in water. The Canadian product labels already include a statement prohibiting discharge of effluents into lakes, streams, rivers or ponds; therefore, the PMRA requires no additional mitigation measures.

3.3 Pest Control Product Policy Considerations

3.3.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, namely, CEPA-toxic or equivalent, predominantly anthropogenic, persistent and bio-accumulative.

During the re-evaluation process, iodocarb was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy,* and evaluated against the Track 1 criteria for persistence and bioaccumulation. In order for iodocarb or its transformation products to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met.

- Persistence. Iodocarb was observed to have half-life values of less than 3 hours in soil and 139 days in buffer solution which are below the TSMP Track 1 criteria (half-life in soil or water > 182 days). Iodocarb does not meet the criterion for persistence.
- Bioaccumulation. The *n*-octanol–water partition coefficient (log K_{ow}) ranging from 2.3 to 2.88 is below the TSMP Track 1 criterion (log $K_{ow} \geq 5.0$). Iodocarb does not meet the criterion for bioaccumulation.

On this basis, it is concluded that the use of iodocarb is not expected to result in the entry of Track 1 substances in the environment.

3.3.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of iodocarb, contaminants in the technical are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

Technical grade Iodocarb does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

4.0 Incident Reports

Starting in April 2007, registrants were required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

There were no incident reports submitted for iodocarb as of March 2, 2010.

5.0 Organization for Economic Co-operation and Development Status of Iodocarb

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 30 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Based on the current available information, the iodocarb use has not been prohibited or restricted in any of the OECD member states.

As described earlier in this document, the United States, also an OECD member, assessed the registration of all uses of iodocarb in 1997 and concluded using iodocarb as a pesticide does not result in unreasonable adverse effects to human health or the environment provided the risk-reduction measures recommended in the RED document were implemented.

The Canadian re-evaluation of iodocarb is largely based on the 1997 USEPA assessments. As described in Section 3.1 and 3.2 above, the PMRA has found the USEPA human health and environmental risk conclusions to be relevant to the use of iodocarb in Canada and requires measures to further protect workers and individuals in residential settings.

6.0 Proposed Re-evaluation Decision

The PMRA has determined that iodocarb is acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment.

- Personal protective equipment consisting of a long-sleeved shirt, long pants, chemical-resistant gloves and goggles for workers handling iodocarb end-use products and for workers involved in maintenance and repair activities. In addition, dust filtering respirator protection is required during handling if there is a potential for dust generation.
- Prohibition of the use of iodocarb-treated materials for food packaging.
- Limitation of the use of iodocarb-treated textiles to non-apparel use only.
- Prohibition of the use of iodocarb-treated textiles in residential settings,
- Prohibition of the use of iodocarb-treated plastic for the production of children toys and other products which may come in contact with children (for example, plastic chair, plastic bottles).

The labels of Canadian end-use products must be amended to include the label statements listed in Appendix IV. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

The registrant of the technical grade active ingredient is required to submit data as a condition of continued registration under Section 12 of the *Pest Control Products Act*. Appendix I lists data requirements.

It should be noted that for end-use products containing more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

7.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and DACO tables can be found on our website at www.healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for iodocarb is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

a.i.	active ingredient
bw	body weight
CAS	Chemical Abstracts Service
DACO	data code
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
mg	milligram(s)
MOE	margin of exposure
nm	nanometre
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PCPA	*Pest Control Products Act*
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
RVD	Re-evaluation Decision
RQ	risk quotient
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Additional Data Requirements

I) The following data are required as a condition of continued registration under section 12 of the PCPA. The registrant of technical iodocarb will be required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter that will be sent when a re-evaluation decision is made.

DACO 5.2	Use Description Scenario (iodocarb use as a material preservative in metal working fluids)
DACO 5.6	Post-application: Passive Dosimetry Data (for workers handling iodocarb-treated metal working fluids and/or involved in maintenance/clean-up activities)

Appendix II Registered Products Containing Iodocarb as of March 2, 2010

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (% w/w)
21750	TGAI	Troy Chemical Corporation	Polyphase P100	Soluble Powder	97%
28422	TGAI	Arch Chemical, Inc.	Omacide ® IPBC 100 Technical Powder Fungicide	Dust or Powder	97%
28583	TGAI	ISP Canada Corp.	Fungitrol 400S Fungicide Technical	Solid	99.5%
21751	MA	Troy Chemical Corporation	Polyphase AF-1	Solution	40%
23531	MA	Troy Chemical Corporation	Polyphase EC-17	Emulsifable Concentrate	17%
24141	MA	Troy Chemical Corporation	Polyphase P-20T	Solution	20%
29260	MA	Troy Chemical Corporation	Polyphase PW20	Solution	20%
25757	Commercial	Lonza Inc.	Dantogard Plus Preservative	Soluble Powder	5.0%
27100	Commercial	Thomson Research Associates	Ultra-Fresh BC-40 Industrial Fungicide	Solution	40%
28173	Commercial	Troy Chemical Corporation	Polyphase 641	Solution	20%
28177	Commercial	Troy Chemical Corporation	Polyphase CST-1	Solution	20%
29390	Commercial	Micropel LLC	Micropel A285	Solution	15%
29419	Commercial	Arch Chemicals Inc.	Omacide IPBC 30 Industrial Fungicide	Solution	30%
29420	Commercial	Arch Chemicals Inc.	Omacide IPBC 100 Industrial Fungicide	Powder	97%
29421	Commercial	Arch Chemicals Inc.	Omacide IPBC 40 Industrial Fungicide	Solution	40%

Appendix III Toxicological Endpoints for Iodocarb Health Risk Assessments

Exposure Scenario	Dose (mg/kg bw/day)	Study	UF/SF or MOE[a]
Short-/Intermediate-term dermal exposure	Dermal NOEL = 200 mg a.i./kg bw/day	Subchronic dermal toxicity study in the rat	100
Chronic inhalation and dermal	Oral NOEL = 20 mg a.i./kg bw/day	Chronic toxicity/carcinogenicity study in the rat	100

a UF/SF refers to total of uncertainty and/or safety factors for dietary assessments. MOE refers to desired margin of exposure for occupational or residential assessments.

Appendix IV Label Amendments for Products Containing Iodocarb

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

I) For material preservative uses the following statements are proposed to be included in the **PRECAUTIONS** section:

Workers must wear a long-sleeved shirt, long pants, chemical resistant gloves and goggles or a face shield during mixing, loading, clean-up and repair. In addition, dust filtering respirator protection is required during handling if there is a potential for dust generation.

Follow manufacturer's instructions for cleaning/maintaining personal protective equipment. If no such instructions exist for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry.

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove personnel protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible wash thoroughly.

II) For material preservative uses the following statements are proposed to be included in the **DIRECTION FOR USE** section:

DO NOT use for plastic for toys.

Do NOT use for textile for apparel.

DO NOT use on any fabric where prolonged skin contact may occur. Treated textiles preserved with iodocarb are not to be used in residential settings where bystanders including children may potentially contact treated textiles. This includes around homes, schools, parks, playgrounds, playing fields, public buildings or any other areas where the general public including children could be exposed.

III) For material preservative uses (plastic, adhesives and paper products) of iodocarb the following label statement must be included on the **primary panel**:

Products containing this antimicrobial pesticide are not to be used in food packaging materials or food contact products.

IV) The following statements must be included in the **ENVIRONMENTAL HAZARDS** section:

Toxic to aquatic organisms.

V) The following label statements must be included in the **DIRECTIONS FOR USE** section:

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

DO NOT discharge effluents containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

References

Studies considered in the Chemistry Assessment

LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

PMRA Document Number	Reference
1248312	1994, Olin Corporation, Product Chemistry for: 3-Iodo-2-Propynylbutylcarbamate (Omacide IPBC 100), N/S, DACO: 2.1,2.10,2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.13.1,2.13.2,2.13.3,2.13.4,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6
1248314	1994, Physical and Chemical Properties of 3-Iodo-2-Propynylbutylcarbamate (Omacide IPBC), 93B021PBC, DACO: 2.1,2.10,2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.13.1,2.13.2,2.13.3,2.13.4,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2
1248612	1994, Amendment to: Product Chemistry: For 3-Iodo-2- Propynylbutylcarbamate (Omacide IPBC 100)., DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.13.1,2.13.2,2.13.3,2.13.4 CBI
1260314	2001, Product Chemistry, Chemical and Physical Properties, Manufacturing-Use Product Chemistry Data and Confidential Business Attachment and Appendix 1-9 Material Safety Data Sheets, DACO: 0.9.1,2.1,2.11.1,2.11.2,2.11.3,2.11.4,2.14.1,2.14.10,2.14.11,2.14.
1260316	2001, Fungitrol 400 Fungicide Five-Batch Analysis on Technical Grade Active Ingredient, DNN130/004612, DACO: 2.13.3 CBI
1260317	2001, Fungitrol 400 Fungicide Physico-Chemical Properties, DNN129/004571, DACO: 2.14.1,2.14.10,2.14.11,2.14.13,2.14.2,2.14.3,2.14.4,2.14.6,2.14.7,2.14.8,2.14.9,2.16 CBI
1452914	2007, Fungitrol 400S Technical Starting Material and Manufacturing Process, DACO: 2.11 CBI
1452916	2007, Carbamic acid,Butyl-,3-iodo-2-propynyl ester, MTJ0006/073357, DACO: 2.13.3 CBI
1452917	2007, Carbamic Acid, butyl-,3-iodo-2-propynyl ester Physico-Chemical Properties, MTJ0004/073390, DACO: 2.14 CBI
1617753	Chemistry data used to support a Technical class product. IPB-TRY-1, DACO: 2.99